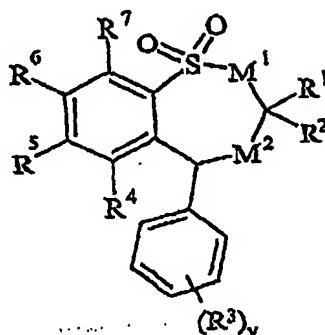


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Claims

1. A compound of formula (I):



(I)

wherein

M^1 is $-CH_2-$ or $-NR^{21}-$;

M^2 is $-CR^{22}R^{23}-$ or $-NR^{24}-$; provided that if M^1 is $-NR^{21}-$, M^2 is $-CR^{22}R^{23}-$;

One of R^1 and R^2 are selected from hydrogen, C_{1-6} alkyl or C_{2-6} alkenyl and the other is selected from C_{1-6} alkyl or C_{2-6} alkenyl;

R^3 is selected from halo, nitro, cyano, hydroxy, amino, carboxy, carbamoyl, mercapto, sulphamoyl, C_{1-6} alkyl, C_{2-6} alkenyl, C_{2-6} alkynyl, C_{1-6} alkoxy, C_{1-6} alkanoyl, C_{1-6} alkanoyloxy, $N-(C_{1-6}alkyl)amino$, $N,N-(C_{1-6}alkyl)_2amino$, $C_{1-6}alkanoylamino$, $N-(C_{1-6}alkyl)carbamoyl$, $N,N-(C_{1-6}alkyl)_2carbamoyl$, $C_{1-6}alkylS(O)_a$ wherein a is 0 to 2, $C_{1-6}alkoxycarbonyl$, $N-(C_{1-6}alkyl)sulphamoyl$ and $N,N-(C_{1-6}alkyl)_2sulphamoyl$;

v is 0-5;

one of R^5 and R^6 is a group of formula (IA):



(IA)

R^4 and R^7 and the other of R^5 and R^6 are independently selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carboxy, carbamoyl, mercapto, sulphamoyl, C_{1-4} alkyl, C_{2-4} alkenyl, C_{2-4} alkynyl, C_{1-4} alkoxy, C_{1-4} alkanoyl, C_{1-4} alkanoyloxy, $N-(C_{1-4}alkyl)amino$, $N,N-(C_{1-4}alkyl)_2amino$, $C_{1-4}alkanoylamino$, $N-(C_{1-4}alkyl)carbamoyl$, $N,N-(C_{1-4}alkyl)_2carbamoyl$, $C_{1-4}alkylS(O)_a$ wherein a is 0 to 2, $C_{1-4}alkoxycarbonyl$,

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N-(C₁₋₄alkyl)sulphamoyl and *N,N*-(C₁₋₄alkyl)₂sulphamoyl; wherein R⁴ and R⁷ and the other of R⁵ and R⁶ may be optionally substituted on carbon by one or more R²⁵;

Z is -O-, -N(R^a)-, -S(O)_b- or -CH(R^a)-; wherein R^a is hydrogen or C₁₋₆alkyl and b is 0-2;

R⁸ is hydrogen, C₁₋₄alkyl, carbocyclyl or heterocyclyl; wherein R⁸ may be optionally substituted on carbon by one or more substituents selected from R²⁶; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R²⁷;

R⁹ is hydrogen or C₁₋₄alkyl;

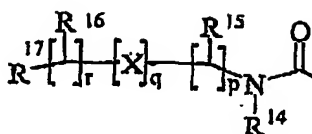
R¹⁰ and R¹¹ are independently selected from hydrogen, C₁₋₄alkyl, carbocyclyl or heterocyclyl; or R¹⁰ and R¹¹ together form C₂₋₆alkylene; wherein R¹⁰ and R¹¹ or R¹⁰ and R¹¹ together may be independently optionally substituted on carbon by one or more substituents selected from R²⁸; and wherein if said heterocyclyl contains an -NH- moiety, that nitrogen may be optionally substituted by one or more R²⁹;

R¹² is hydrogen, C₁₋₄alkyl, carbocyclyl or heterocyclyl; wherein R¹² may be optionally substituted on carbon by one or more substituents selected from R³⁰; and wherein if said heterocyclyl contains an -NH- moiety, that nitrogen may be optionally substituted by one or more R³¹;

R¹³ is hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl, C₁₋₁₀alkyl, C₂₋₁₀alkenyl, C₂₋₁₀alkynyl, C₁₋₁₀alkoxy, C₁₋₁₀alkoxycarbonyl, C₁₋₁₀alkanoyl, C₁₋₁₀alkanoyloxy, *N*-(C₁₋₁₀alkyl)amino, *N,N*-(C₁₋₁₀alkyl)₂amino, *N,N,N*-(C₁₋₁₀alkyl)₃ammonio, C₁₋₁₀alkanoylamino, *N*-(C₁₋₁₀alkyl)carbamoyl, *N,N*-(C₁₋₁₀alkyl)₂carbamoyl, C₁₋₁₀alkylS(O)_a wherein a is 0 to 2, *N*-(C₁₋₁₀alkyl)sulphamoyl, *N,N*-(C₁₋₁₀alkyl)₂sulphamoyl, *N*-(C₁₋₁₀alkyl)sulphamoylamino, *N,N*-(C₁₋₁₀alkyl)₂sulphamoylamino, C₁₋₁₀alkoxycarbonylamino, carbocyclyl, carbocyclylC₁₋₁₀alkyl, heterocyclic group, heterocyclylC₁₋₁₀alkyl, carbocyclyl-(C₁₋₁₀alkylene)_a-R³²-(C₁₋₁₀alkylene)_b or heterocyclyl-(C₁₋₁₀alkylene)_a-R³³-(C₁₋₁₀alkylene)_b; wherein R¹³ may be optionally substituted on carbon by one or more substituents selected from R³⁶; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R³⁷; or R¹³ is a group of formula (IB):

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(IB)

wherein:

X is $-\text{N}(\text{R}^{38})-$, $-\text{N}(\text{R}^{38})\text{C}(\text{O})-$, $-\text{O}-$, and $-\text{S}(\text{O})_a-$; wherein a is 0-2 and R^{38} is hydrogen or C_{1-4} alkyl;

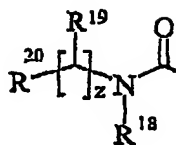
R^{14} is hydrogen or C_{1-4} alkyl;

R^{15} and R^{16} are independently selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, C_{1-6} alkyl, C_{2-6} alkenyl, C_{2-6} alkynyl, C_{1-6} alkoxy, C_{1-6} alkanoyl, C_{1-6} alkanoyloxy, $N-(\text{C}_{1-6}\text{alkyl})$ amino, $N,N-(\text{C}_{1-6}\text{alkyl})_2$ amino, C_{1-6} alkanoylamino, $N-(\text{C}_{1-6}\text{alkyl})$ carbamoyl, $N,N-(\text{C}_{1-6}\text{alkyl})_2$ carbamoyl, $\text{C}_{1-6}\text{alkylS}(\text{O})_a$ wherein a is 0 to 2, C_{1-6} alkoxycarbonyl, $N-(\text{C}_{1-6}\text{alkyl})$ sulphamoyl, $N,N-(\text{C}_{1-6}\text{alkyl})_2$ sulphamoyl, carbocyclyl or heterocyclic group; wherein R^{15} and R^{16} may be independently optionally substituted on carbon by one or more substituents selected from R^{41} ; and wherein if said heterocyclyl contains an $-\text{NH}-$ group, that nitrogen may be optionally substituted by a group selected from R^{42} ;

R^{17} is selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl, C_{1-10} alkyl, C_{2-10} alkenyl, C_{2-10} alkynyl, C_{1-10} alkoxy, C_{1-10} alkanoyl, C_{1-10} alkanoyloxy, $N-(\text{C}_{1-10}\text{alkyl})$ amino, $N,N-(\text{C}_{1-10}\text{alkyl})_2$ amino, C_{1-10} alkanoylamino, $N-(\text{C}_{1-10}\text{alkyl})$ carbamoyl, C_{1-10} alkoxycarbonyl, $N,N-(\text{C}_{1-10}\text{alkyl})_2$ carbamoyl, $\text{C}_{1-10}\text{alkylS}(\text{O})_a$ wherein a is 0 to 2, $N-(\text{C}_{1-10}\text{alkyl})$ sulphamoyl, $N,N-(\text{C}_{1-10}\text{alkyl})_2$ sulphamoyl, $N-(\text{C}_{1-10}\text{alkyl})$ sulphamoylamino, $N,N-(\text{C}_{1-10}\text{alkyl})_2$ sulphamoylamino, carbocyclyl, carbocyclyl C_{1-10} alkyl, heterocyclic group, heterocyclyl C_{1-10} alkyl, carbocyclyl $-(\text{C}_{1-10}\text{alkylene})_e-\text{R}^{43}-(\text{C}_{1-10}\text{alkylene})_f$ or heterocyclyl $-(\text{C}_{1-10}\text{alkylene})_e-\text{R}^{44}-(\text{C}_{1-10}\text{alkylene})_f$; wherein R^{17} may be optionally substituted on carbon by one or more substituents selected from R^{47} ; and wherein if said heterocyclyl contains an $-\text{NH}-$ group, that nitrogen may be optionally substituted by a group selected from R^{48} ; or R^{17} is a group of formula (IC):

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(IC)

wherein:

R^{18} is selected from hydrogen or C_{1-4} alkyl;

R^{19} is selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, C_{1-6} alkyl, C_{2-6} alkenyl, C_{2-6} alkynyl, C_{1-6} alkoxy, C_{1-6} alkanoyl, C_{1-6} alkanoyloxy, N -(C_{1-6} alkyl)amino, N,N -(C_{1-6} alkyl) $_2$ amino, C_{1-6} alkanoylamino, N -(C_{1-6} alkyl)carbamoyl, N,N -(C_{1-6} alkyl) $_2$ carbamoyl, C_{1-6} alkylS(O) $_a$ wherein a is 0 to 2, C_{1-6} alkoxycarbonyl, N -(C_{1-6} alkyl)sulphamoyl, N,N -(C_{1-6} alkyl) $_2$ sulphamoyl, carbocyclyl or heterocyclic group; where R^{19} may be independently optionally substituted on carbon by one or more substituents selected from R^{51} ; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R^{52} ;

R^{20} is selected from halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl, C_{1-10} alkyl, C_{2-10} alkenyl, C_{2-10} alkynyl, C_{1-10} alkoxy, C_{1-10} alkoxycarbonyl, C_{1-10} alkanoyl, C_{1-10} alkanoyloxy, N -(C_{1-10} alkyl)amino, N,N -(C_{1-10} alkyl) $_2$ amino, N,N,N -(C_{1-10} alkyl) $_3$ ammonio, C_{1-10} alkanoylamino, N -(C_{1-10} alkyl)carbamoyl, N,N -(C_{1-10} alkyl) $_2$ carbamoyl, C_{1-10} alkylS(O) $_a$ wherein a is 0 to 2, N -(C_{1-10} alkyl)sulphamoyl, N,N -(C_{1-10} alkyl) $_2$ sulphamoyl, N -(C_{1-10} alkyl)sulphamoylamino, N,N -(C_{1-10} alkyl) $_2$ sulphamoylamino, C_{1-10} alkoxycarbonylamino, carbocyclyl, carbocyclyl C_{1-10} alkyl, heterocyclic group, heterocyclyl C_{1-10} alkyl, carbocyclyl-(C_{1-10} alkylene) $_e$ - R^{53} -(C_{1-10} alkylene) $_f$ or heterocyclyl-(C_{1-10} alkylene) $_g$ - R^{54} -(C_{1-10} alkylene) $_h$; wherein R^{20} may be independently optionally substituted on carbon by one or more R^{57} ; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R^{58} ;

p is 1-3; wherein the values of R^{15} may be the same or different;

q is 0-1;

r is 0-3; wherein the values of R^{16} may be the same or different;

m is 0-2; wherein the values of R^{12} may be the same or different;

n is 1-2; wherein the values of R^8 may be the same or different;

z is 0-3; wherein the values of R^{10} may be the same or different;

R^{21} is selected from hydrogen or C_{1-6} alkyl;

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R^{22} and R^{23} are independently selected from hydrogen, hydroxy, amino, mercapto, C_{1-6} alkyl, C_{1-6} alkoxy, N -(C_{1-6} alkyl)amino, N,N -(C_{1-6} alkyl)₂amino, C_{1-6} alkylS(O)_a wherein a is 0 to 2;

R^{24} is selected from hydrogen, hydroxy, C_{1-6} alkyl, C_{1-4} alkoxy and C_{1-6} alkanoyloxy;

R^{25} is selected from halo, nitro, cyano, hydroxy, amino, carboxy, carbamoyl, mercapto, sulphamoyl, C_{1-4} alkyl, C_{2-4} alkenyl, C_{2-4} alkynyl, C_{1-4} alkoxy, C_{1-4} alkanoyl, C_{1-4} alkanoyloxy, N -(C_{1-4} alkyl)amino, N,N -(C_{1-4} alkyl)₂amino, C_{1-4} alkanoylamino, N -(C_{1-4} alkyl)carbamoyl, N,N -(C_{1-4} alkyl)₂carbamoyl, C_{1-4} alkylS(O)_a wherein a is 0 to 2, C_{1-4} alkoxycarbonyl, N -(C_{1-4} alkyl)sulphamoyl and N,N -(C_{1-4} alkyl)₂sulphamoyl; wherein R^{25} may be independently optionally substituted on carbon by one or more R^{67} ;

R^{26} , R^{28} , R^{30} , R^{36} , R^{41} , R^{47} , R^{51} and R^{57} are independently selected from halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl, C_{1-10} alkyl, C_{2-10} alkenyl, C_{2-10} alkynyl, C_{1-10} alkoxy, C_{1-10} alkanoyl, C_{1-10} alkanoyloxy, C_{1-10} alkoxycarbonyl, N -(C_{1-10} alkyl)amino, N,N -(C_{1-10} alkyl)₂amino, N,N,N -(C_{1-10} alkyl)₃ammonio, C_{1-10} alkanoylamino, N -(C_{1-10} alkyl)carbamoyl, N,N -(C_{1-10} alkyl)₂carbamoyl, C_{1-10} alkylS(O)_a wherein a is 0 to 2, N -(C_{1-10} alkyl)sulphamoyl, N,N -(C_{1-10} alkyl)₂sulphamoyl, N -(C_{1-10} alkyl)sulphamoylamino, N,N -(C_{1-10} alkyl)₂sulphamoylamino, C_{1-10} alkoxycarbonylamino, carbocyclyl, carbocyclyl C_{1-10} alkyl, heterocyclic group, heterocyclyl C_{1-10} alkyl, carbocyclyl-(C_{1-10} alkylene)_a- R^{59} -(C_{1-10} alkylene)_c or heterocyclyl-(C_{1-10} alkylene)_e- R^{60} -(C_{1-10} alkylene)_h; wherein R^{26} , R^{28} , R^{30} , R^{36} , R^{41} , R^{47} , R^{51} and R^{57} may be independently optionally substituted on carbon by one or more R^{63} ; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R^{64} ;

R^{27} , R^{29} , R^{31} , R^{37} , R^{42} , R^{48} , R^{52} , R^{58} and R^{64} are independently selected from C_{1-6} alkyl, C_{1-6} alkanoyl, C_{1-6} alkylsulphonyl, sulphamoyl, N -(C_{1-6} alkyl)sulphamoyl, N,N -(C_{1-6} alkyl)₂sulphamoyl, C_{1-6} alkoxycarbonyl, carbamoyl, N -(C_{1-6} alkyl)carbamoyl, N,N -(C_{1-6} alkyl)₂carbamoyl, benzyl, phenethyl, benzoyl, phenylsulphonyl and phenyl;

R^{32} , R^{33} , R^{43} , R^{44} , R^{53} , R^{54} , R^{59} and R^{60} are independently selected from -O-, -NR⁶⁵-, -S(O)_x-, -NR⁶⁵C(O)NR⁶⁶-, -NR⁶⁵C(S)NR⁶⁶-, -OC(O)N=C-, -NR⁶⁵C(O)- or -C(O)NR⁶⁵-; wherein R^{65} and R^{66} are independently selected from hydrogen or C_{1-6} alkyl, and x is 0-2;

R^{63} and R^{67} are independently selected from halo, hydroxy, cyano, carbamoyl, ureido, amino, nitro, carbamoyl, mercapto, sulphamoyl, trifluoromethyl, trifluoromethoxy, methyl, ethyl, methoxy, ethoxy, vinyl, allyl, ethynyl, methoxycarbonyl, formyl, acetyl, formamido,

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acetylamino, acetoxy, methylamino, dimethylamino, *N*-methylcarbamoyl, *N,N*-dimethylcarbamoyl, methylthio, methylsulphinyl, mesyl, *N*-methylsulphamoyl and *N,N*-dimethylsulphamoyl; and

e, f, g and h are independently selected from 0-2;

or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof; with the proviso that said compound is not:

1,1-dioxo-3-isopropyl-5-phenyl-8-[*N*-(propyl)carbamoylmethoxy]-2,3,4,5-tetrahydro-1,4-benzothiazepine; or

1,1-dioxo-3-isopropyl-5-phenyl-7-iodo-8-[*N*-(propyl)carbamoylmethoxy]-2,3,4,5-tetrahydro-1,4-benzothiazepine.

2. A compound of formula (I) according to claim 1 wherein M^1 is $-CH_2-$ and M^2 is $-CR^{22}R^{23}-$; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.
3. A compound of formula (I) according to claim 1 wherein M^1 is $-CH_2-$ and M^2 is $-NR^{24}-$; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.
4. A compound of formula (I) according to claim 1 or 2 wherein R^{22} and R^{23} are independently selected from hydrogen and hydroxy; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.
5. A compound of formula (I) according to claim 1 or 3 wherein R^{24} is hydrogen; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.
6. A compound of formula (I) according to any one of claims 1-5 wherein R^1 and R^2 are C_{1-4} alkyl; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.
7. A compound of formula (I) according to any one of claims 1-6 wherein v is 0; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

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8. A compound of formula (I) according to any one of claims 1-7 wherein R^4 and R^7 are hydrogen; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.
9. A compound of formula (I) according to any one of claims 1-8 wherein the R^5 or R^6 not selected from a group of formula (IA) is hydrogen or methylthio; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.
10. A compound of formula (I) according to any one of claims 1-9 wherein one of R^5 and R^6 is a group of formula (IA) (as depicted above); wherein:
- Z is -O- or -S(O)_b-; wherein b is 0;
 - R^8 is hydrogen;
 - R^9 is hydrogen;
 - R^{10} and R^{11} are independently selected from hydrogen or carbocyclyl; wherein R^{10} and R^{11} may be independently optionally substituted on carbon by one or more substituents selected from R^{28} ;
 - R^{13} is a group of formula (IB) (as depicted above);
 - R^{14} is hydrogen;
 - R^{15} is hydrogen;
 - R^{17} is C₁₋₁₀alkyl; wherein R^{17} may be optionally substituted on carbon by one or more substituents selected from R^{47} ; or R^{17} is a group of formula (IC) (as depicted above) wherein:
 - R^{18} is selected from hydrogen;
 - R^{19} is selected from hydrogen;
 - R^{20} is C₁₋₁₀alkyl; wherein R^{20} may be independently optionally substituted on carbon by one or more R^{57} ;
 - p is 1;
 - q is 0;
 - r is 0;
 - m is 0;
 - n is 1;
 - z is 1; and
 - R^{28} , R^{47} and R^{57} are independently selected from halo and hydroxy
- or a pharmaceutically acceptable salt, solvato, solvate of such a salt or a prodrug thereof.

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11. A compound of formula (I) wherein:

M^1 is $-CH_2-$;

M^2 is $-CR^{22}R^{23}-$ and $-NR^{24}-$;

R^{22} and R^{23} are independently selected from hydrogen and hydroxy;

One of R^1 and R^2 is ethyl and the other is butyl;

v is 0;

R^4 and R^7 are hydrogen;

One of R^5 or R^6 is selected from a group of formula (IA) (as depicted above) and the other is hydrogen or methylthio;

Z is $-O-$ or $-S(O)_b-$; wherein b is 0;

R^8 is hydrogen;

R^9 is hydrogen;

R^{10} and R^{11} are independently selected from hydrogen, 2-fluorophenyl or carbocyclyl;

R^{13} is a group of formula (IB) (as depicted above);

R^{14} is hydrogen;

R^{15} is hydrogen;

R^{17} is pentyl substituted by 5 hydroxy; or R^{17} is a group of formula (IC) (as depicted above) wherein:

R^{18} is selected from hydrogen;

R^{19} is selected from hydrogen;

R^{20} is pentyl substituted by 5 hydroxy;

p is 1;

q is 0;

r is 0;

m is 0;

n is 1; and

z is 1;

or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

12. A compound of formula (I) selected from:

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(+/-)-trans-1,1-dioxo-3-ethyl-3-butyl-5-phenyl-7-methylthio-8-(N-{(R)- α -[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]benzyl}carbamoylmethoxy)-2,3,4,5-tetrahydro-1,4-benzothiazepine;

(+/-)-trans-1,1-dioxo-3-ethyl-3-butyl-5-phenyl-7-methylthio-8-(N-{(R)- α -[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]benzyl}carbamoylmethoxy)-2,3,4,5-tetrahydro-1,4-benzothiazepine;

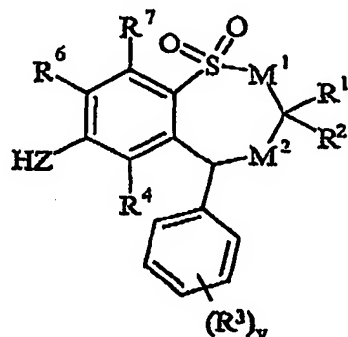
1,1-dioxo-3-ethyl-3-butyl-4-hydroxy-5-phenyl-7-(N-{ α -[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]-2-fluorobenzyl}carbamoylmethylthio)-2,3,4,5-tetrahydrobenzothiepine; or

1,1-dioxo-3-butyl-3-ethyl-4-hydroxy-5-phenyl-7-(N-{1-[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]-1-(cyclohexyl)methyl}carbamoylmethylthio)-2,3,4,5-tetrahydrobenzothiepine;

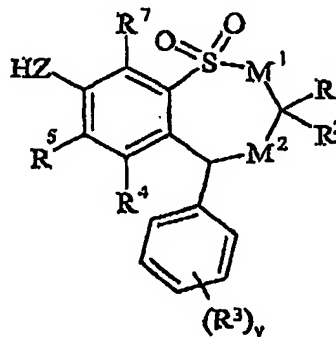
or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

13. A process for preparing a compound of formula (I) or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in anyone of claims 1-12, which process (wherein variable groups are, unless otherwise specified, as defined in claim 1) comprises of:

Process 1): for compounds of formula (I) wherein Z is -O-, -NR^a or -S-; reacting a compound of formula (IIa) or (IIb):



(IIa)

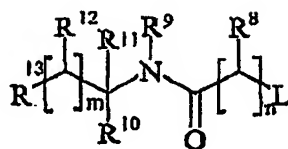


(IIb)

with a compound of formula (III):

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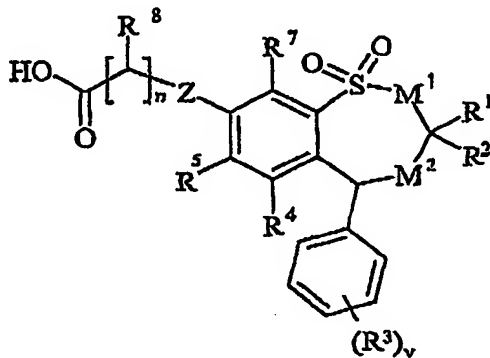
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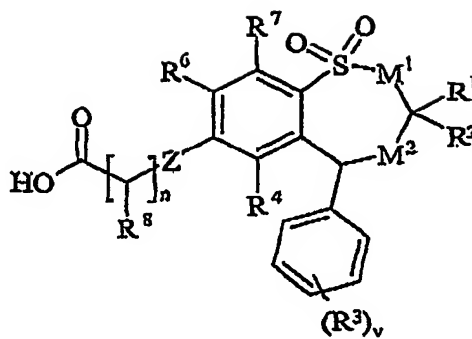
(III)

wherein L is a displaceable group;

Process 2): reacting an acid of formula (IVa) or (IVb):

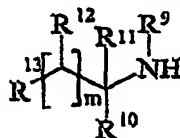


(IVa)



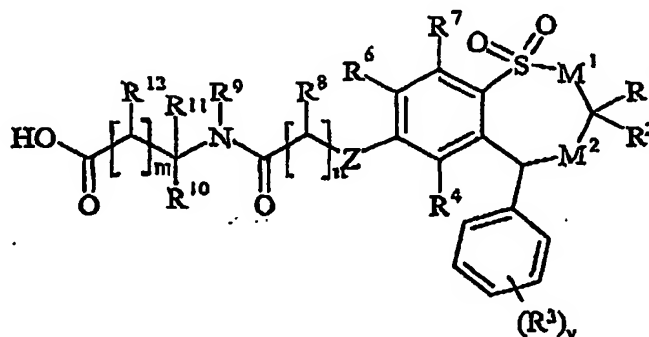
(IVb)

or an activated derivative thereof; with an amine of formula (V):



(V);

Process 3): for compounds of formula (I) wherein R¹³ is a group of formula (IB); reacting an acid of formula (VIa):

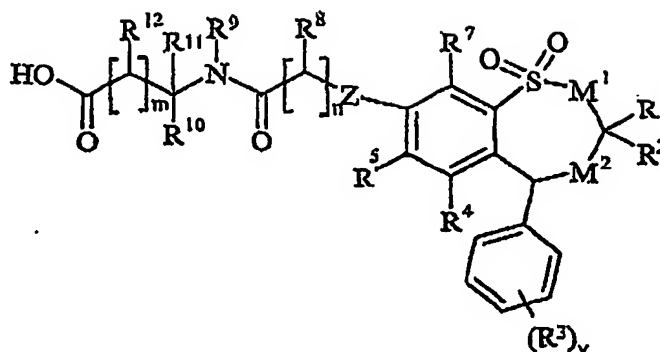


(VIa)

or (VIb):

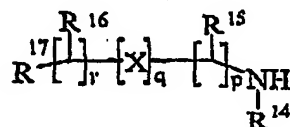
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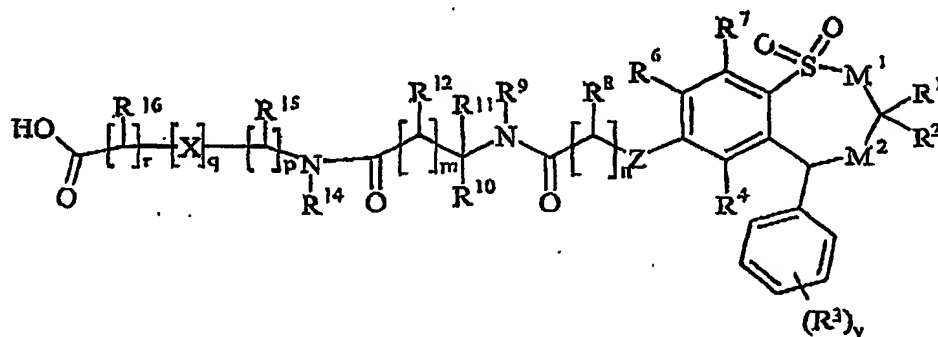
(VIb)

with an amine of formula:



(VI)

Process 4): for compounds of formula (I) wherein R^{13} is a group of formula (IB) and R^{17} is a group of formula (IC); reacting an acid of formula (VIIIa):

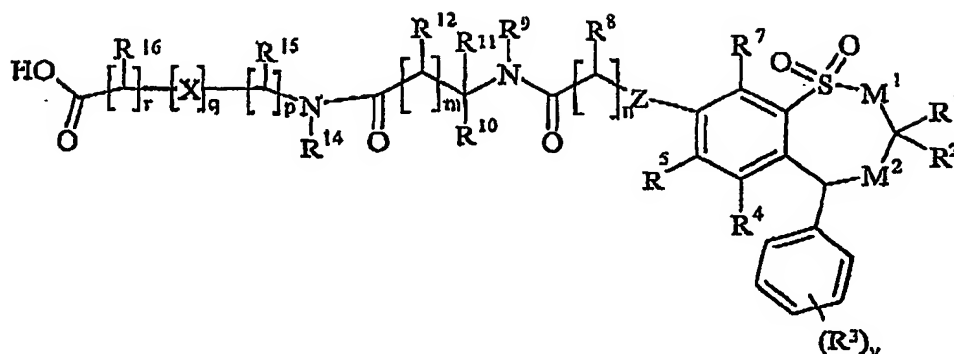


(VIIIa)

or (VIIIb)

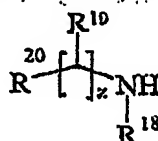
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(VIIIb)

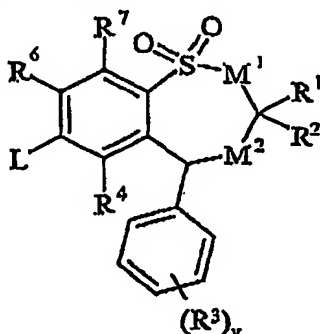
or an activated derivative thereof; with an amine of formula (IX):



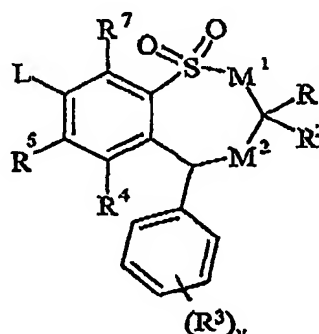
(IX)

or

Process 5) for compounds of formula (I) wherein one of R⁵ and R⁶ are independently selected from C₁₋₆alkylthio optionally substituted on carbon by one or more R²⁵; reacting a compound of formula (Xa) or (Xb):



(Xa)



(Xb)

wherein L is a displaceable group; with a thiol of formula (XI):



(XI)

wherein R^m is C₁₋₆alkylthio optionally substituted on carbon by one or more R²⁵,
and thereafter if necessary or desirable:

i) converting a compound of the formula (I) into another compound of the formula (I);

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ii) removing any protecting groups;

iii) forming a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug.

14. A compound of the formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12 for use as a medicament.

15. A compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12 for use in a method of prophylactic or therapeutic treatment of a warm-blooded animal, such as man.

16. The use of a compound of the formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12 in the manufacture of a medicament for use in the production of an IBAT inhibitory effect in a warm-blooded animal, such as man.

17. A method for producing an IBAT inhibitory effect in a warm-blooded animal, such as man, in need of such treatment which comprises administering to said animal an effective amount of a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12.

18. A pharmaceutical composition which comprises a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12, in association with a pharmaceutically-acceptable diluent or carrier.

19. A combination comprising a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12, and an HMG Co-A reductase inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

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20. A combination comprising a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12, and a bile acid binder.

21. A combination comprising a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12, and an HMG Co-A reductase inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, and a bile acid binder.

22. A combination according to claim 19 or claim 21 wherein the HMG Co-A reductase inhibitor is atorvastatin, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

23. A combination according to claim 19 or claim 21 wherein the HMG Co-A reductase inhibitor is rosuvastatin, or a pharmaceutically acceptable salt thereof.

24. A combination comprising a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12 and a PPAR alpha and/or gamma agonist, or a pharmaceutically acceptable salt thereof.

25. A composition according to claim 24 wherein the PPAR alpha and/or gamma agonist is (S)-2-ethoxy-3-[4-(2-{4-methanesulphonyloxyphenyl}ethoxy)phenyl]propanoic acid or a pharmaceutically acceptable salt thereof.

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